

**REMARKS**

Claims 1-9 and 55-57 were pending in the previous response dated September 5, 2006. Claims 2, 7, and 55-57 have been canceled. Claims 1, 3-6, 8, and 9 have been amended to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 58-62 have been newly added. Support for amended claim 1 can be found in the specification at col. 3, lines 22-23 (“enhancing the immune function”), col. 1, lines 48-49 (“flavin mononucleotide and flavin adenine dinucleotide”), col. 1, line 33, col. 2, line 4, and col. 3, line 13. Support for newly presented claim 58 can be found at col. 2, lines 29-30, and Example 2. Support for newly presented claims 59-62 can be found in the specification *inter alia* and at Example 6 and Table 7. Applicants believe no new matter is introduced with this amendment. After entry of these amendments, claims 1, 3-6, 8-9, and 58-62 will be pending.

**Defective Oath**

Applicants will submit a proper supplemental oath/declaration upon a showing of patentable subject matter.

**Application Objection under 37 CFR 1.172(a)**

Upon a showing of patentable subject matter, Applicants will submit a proper consent of assignee establishing ownership in the patent for which reissue is being requested.

**Claim Objections**

Claim 7 was objected to because of certain misspellings. Claim 7 has been canceled with this Response.

**Claim Rejections – 35 U.S.C. § 112 1<sup>st</sup> Paragraph, Enablement**

Claims 1-9 and 55-57 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner states “the specification, while being enabling for increasing the immune response of animals inoculated with *E. coli*, does not reasonably provide enablement for ‘protecting against infections’ generally or specifically treating *E. coli* infections” (OA, p. 4.). Furthermore, the

office action states that the term “treated” means “eradicated” or “rendered impotent”, (OA, p. 8). Applicants do not agree with this statement. The term “treat” or “treatment” means “the management and care of a patient for the purpose of treating a disease or disorder,” (Dorland’s Medical Dictionary, 26<sup>th</sup> ed., W. B. Saunders Co., Philadelphia, 1994). Treating a disease or disorder encompasses more than eradicating or rendering impotent. For example, lessening symptoms (e.g., reduce fever) is one way to treat a disorder.

However, Applicants, while not acquiescing in the propriety of this rejection, have canceled claims 2, 7, and 55-57, and amended claims 1, 3-6 and 8-9, to recite “a method for enhancing the immune response in a mammal...” The Examiner has indicated that such subject matter is enabled, and Applicants respectfully request that this rejection should be reconsidered in light of this amendment and withdrawn.

#### **Claim Rejections – 35 U.S.C. § 112, First Paragraph, Written Description**

Claims 1, 3-9 and 55-57 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner argues that there is insufficient written description for the terms “riboflavin derivative”, antibiotic”, and “water-soluble polymer” (OA, p. 9). Applicants have amended claim 1 by substituting the terms “flavin mononucleotide” and “flavin adenine dinucleotide” for “riboflavin derivative”. Applicants have amended claim 6 by adding the language “at least one water-soluble polymer selected from the group consisting of polyvinyl pyrrolidone, sodium carboxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, sodium chondroitin sulfate, polyethylene-hardened castor oil, polyoxysorbitan fatty acid esters and polyvinyl alcohol”.

Applicants disagree with the Examiner that there is insufficient written description for the term “antibiotic”. One of skill in the art would have known at the time of the filing what antibiotics were useful in combating *E. coli* infections. For example, Cephalothin, Nalidixic Acid, Ampicillin, Sodium Colistimethate, Nitrofurantoin, Tetracycline, Gentamicin, Kanamycin, Trimethoprim-Sulfamethoxazole, and Sodium Carbencillin are all effective in treating *E. coli* infections (see e.g. U.S. 4,340,671). Therefore, one of skill in the art at the time of the filing of the present application would have known what was meant by the term antibiotic in the context

of treating *E. coli*. Thus, the claims should not be limited to the recitation of amoxicillin, tetracycline and oxycline as suggested by the Examiner. Applicants therefore request reconsideration of this rejection and its withdrawal.

**Claim Rejections – 35 U.S.C. § 112, Second Paragraph**

Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, the Examiner interprets the phrase “protection against infection” to mean “prevention” of infection based on the assumption that the term “treating” means “eradicating or rendering impotent.” The Examiner then concludes that the metes and bounds of claims 1-8 are unclear (OA p. 10). Applicants respectfully disagree with the Examiner’s definition of the term “treating” as noted above. Furthermore, Applicants believe that the Specification clearly defines the phrase “protection against infection” to mean the prevention of infection in a human or an animal by a bacterium or virus after the administration of riboflavin (specification, col. 3, lines 15, 23-24; Table 2 (up to 100% protection); Table 4 (up to 100% protection); Table 5 (up to 100% protection); and Table 6 (up to 100% protection)).

However, while not acquiescing in the propriety of the rejection, Applicants have canceled claims 2 and 7 and have amended claims 1, 3-6 and 8 by substituting “increasing the immune response in a mammal” for “protection against infection”.

Therefore, Applicants respectfully request the Examiner to reconsider this rejection and withdraw it.

**Claim Rejections – 35 USC § 102**

Claims 1-5 are rejected by the Examiner as being anticipated by Wertman and Sypherd; Ajayi et al., Tsyganenko, Zoltowska, or Folkers. As an initial matter, Folkers is related to the treatment of Carpel Tunnel Syndrome which is not caused by bacterial or viral infection. Applicants respectfully request clarification of the rejection of the claims in view of Folkers.

Notwithstanding the foregoing, Applicants have cancelled claim 2 and have amended claims 1 and 3-5 to recite, in relevant part, “a method for enhancing the immune response to *E. coli* in a human or animal in need thereof...” None of the aforementioned references teach the enhancement of the immune response to *E. coli* in a human or an animal. Furthermore, the Folkers reference is directed to the treatment of carpal tunnel syndrome with riboflavin. Folkers does not teach or suggest the use of riboflavin for the enhancement of the immune response to *E. coli* in a human or an animal. Carpel tunnel syndrome is not the result of a bacterial or viral infection and thus is not applicable to the examination of the presently claimed invention. Therefore, in view of the amended claims, and the foregoing arguments, Applicants respectfully request that the Examiner reconsider the rejection and withdraw it.

**Nonstatutory Double Patenting**

Claim 1 is provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over claim 14 of co-pending application No. 10/472,621. Upon notice of allowable claims, Applicants will file either a terminal disclaimer over the cited application or amend the pending claims appropriately.

**CONCLUSIONS**

In view of the remarks set forth above, it is respectfully submitted that this application is in condition for allowance. Accordingly, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is hereby authorized to charge any additional fees that may be due in connection with this Reply to Deposit Account No. 08-0219.

If the Examiner has any questions in regard to this Reply, or any other issue in this case, please call the below signed representative at (617) 526-6404.

Respectfully submitted,

Dated: May 29, 2007



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